



**Medtronic**

Medtronic Neurological  
800 53rd Avenue NE  
Minneapolis, MN 55421.1200 USA  
www.medtronic.com

tel 612.514.5000  
tel 800.328.0810 toll-free  
fax 612.514.5229

September 25, 2000

0616 '00 SEP 26 A9:15

Dockets Management Branch (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**RE: Docket No. 00P-0788; Reclassification of the Totally Implanted Spinal Cord Stimulator**

Dear Dr. Pagano:

On behalf of Medtronic, I am requesting a 60-day extension to the public comment period concerning reclassification of the Totally Implanted Spinal Cord Stimulator so that we may effectively prepare comments. The current public comment period ends on October 6, 2000. I respectfully request that this request become a part of the administrative record.

Thank you for your consideration.

Sincerely,  
Medtronic Neurological

Lynn Switzer  
Director of Regulatory and Clinical

ph.: 763-514-7338  
fax: 763-514-7285  
e-mail: lynn.switzer@medtronic.com

cc: Philip Phillips, FDA  
Celia Witten, FDA

00P-0788

*When Life Depends on Medical Technology*

EXT 1

From: MARY WARREN (612)514-7464  
MEDTRONIC, INC  
800 53RD AVE. N

MINNEAPOLIS, MN, 55421

To: Dockets Management Branch (HFA-305) (301)443-8818  
Docket No. 00P-0788

US Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD, 20852

SHIPPER'S FEDEX ACCOUNT #



**FedEx.**

SHIP DATE: 25SEP00  
WEIGHT: 1 LBS

Ref:



DELIVERY ADDRESS  
TRK # 7918 5781 2673 FORM 0201

PRIORITY OVERNIGHT

IAD

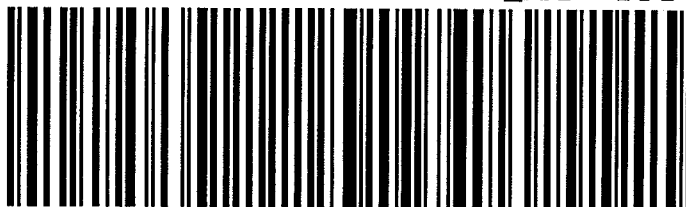
20852-MD-US

**XA GAIA**

TUE

AA

Deliver by:  
26SEP00



## Shipping Label

Schedule Courier

Find a Dropoff Location

Shipping History

Shipment Complete

Cancel Shipment

1. Use the "Print" feature from your browser to send this page to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping label pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.
4. To print a receipt of your shipment, please click on "Shipping History."

## Ship a New Package

Ship Inside U.S.

Ship Outside U.S.

Ship to Same Recipient

Use of this system constitutes your agreement to the service conditions in the current FedEx service Guide, available upon request.

FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.